



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2005-0044]

Not Applying the Mark of Inspection Pending Certain Test Results

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; final policy statement.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it is changing its procedures and will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. This notice responds to the comments FSIS received on the Federal Register notice it issued on April 11, 2011, which announced the Agency's intention to implement this policy, and explains how this policy will apply to domestic and imported product. FSIS did not make any changes to the policy that it announced.

DATES: Effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Background

FSIS is responsible for protecting the nation's meat and poultry supply by making sure that it is safe, wholesome, not adulterated, and properly marked, labeled and packaged. FSIS administers the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et. seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et. seq.) (the Acts). These statutes prohibit anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or poultry products (21 U.S.C. 610 and 458).

On April 11, 2011, FSIS published the notice in the Federal Register, "Not Applying the Mark of Inspection Pending Certain Test Results" (76 FR 19952). The notice explained that the Agency's practice has been to allow products tested for adulterants to bear the mark of inspection, and to enter commerce, even when test results have not been received. FSIS has asked, but had not required, official establishments to maintain control of

products tested for adulterants pending test results. The notice stated that because establishments, including official import inspection establishments, were not consistently maintaining control of product, despite FSIS's request that they do so, adulterated product was entering commerce. In the April 11, 2011, notice, FSIS announced its tentative determination not to apply the mark of inspection until negative results are available and received for any testing for adulterants conducted by the Agency.

In the notice, FSIS stated that the policy would cover non-intact raw beef product or intact raw beef product intended for non-intact use that is tested for Escheriachia coli O157:H7 (E. coli O157:H7). Also, FSIS explained the policy would cover any ready-to-eat products tested for Listeria monocytogenes, E. coli O157:H7, or Salmonella. Similarly, FSIS stated that the policy would cover ready-to-eat product that passed over food contact surfaces that have been tested for the presence of Listeria monocytogenes and Salmonella, pending receipt of negative test results. In the notice, FSIS stated that the policy would not cover raw meat or poultry products tested for Salmonella or other pathogens that FSIS has not designated as adulterants in those products.

In the notice, FSIS stated that the policy would also apply to livestock carcasses subject to FSIS testing for veterinary drugs such as antibiotics, sulfonamides, or avermectins or the feed additive carbadox. FSIS also explained that because of the significant number of poultry carcasses in a lot, the economic effect of holding such a lot, and because, historically, FSIS has not seen residue problems in poultry tested for residues, such product would not need to be held from commerce pending negative test results (76 FR 19955).

#### Comments and FSIS Response

FSIS received 26 comments in response to the notice from industry, domestic and foreign trade organizations, consumer groups, foreign government, and individuals, including FSIS personnel. Commenters supported effective procedures to prevent adulterated product from entering commerce. However, many comments from industry, foreign trade organizations, and foreign governments raised concern about the potential impact this policy would have on small businesses, especially those that produce product with a short-shelf life, and those entities who import product. Commenters also raised other concerns and requested clarification on some points.

## Effect on Small and Very Small Businesses

The majority of the industry commenters raised concerns about the impact of this policy on small businesses and businesses that produce product with a short-shelf life (e.g., fresh sausage, or fresh ground beef, or chicken salad). There was a general concern that establishments may need to hold product for longer than its shelf life. Some commenters emphasized the need for FSIS to pay special attention to the needs of small and very small establishments by providing them sufficient notification of the sample collection (e.g., more than 48 hours) and to provide them the ability to produce smaller batches of product. Also, commenters suggested that FSIS laboratories should prioritize the analysis of samples, in particular samples of ground beef, collected at small and very small establishment. Commenters raised concerns that sample discards would further delay the process and have a negative financial impact on small and very small establishments.

## Response

Before implementing this new policy, FSIS will issue instructions reiterating to inspection program personnel that they are to provide establishments prior notification of sampling for adulterants. FSIS will also issue specific

instructions to address sample collection at small and very small establishments to make it clear that small and very small establishments can produce smaller representative batches of product for sampling. This will help small and very small establishments reduce their lot size on a day when FSIS collects a sample. Thus, for products with short shelf- life, a firm may produce and hold a lot subject to FSIS sampling that is demonstrated by the establishment to be microbiologically independent from other production lots, conduct a clean-up, and then produce other like product eligible to be shipped into commerce. FSIS also intends to provide small and very small establishments with new compliance guidance for how to properly produce representative small batches of product.

FSIS begins testing of all ground beef samples for microbiological pathogen analysis the day of receipt, including Saturdays. Also, FSIS begins testing of all ready-to-eat product samples (e.g., chicken salad) for microbiological pathogen analysis the day of receipt, including Saturdays. FSIS will remain committed to having most negative tests results available in 1 - 2 days. In regard to sample discards, any sample that the FSIS laboratory may discard would occur the day of receipt and would not increase turnaround times in any way.

Additionally, FSIS will consider reducing its frequency of sampling at small and very small establishments that have programs in place that include measures such as purchase specifications that address controls for pathogens in incoming product and product and food contact surface verification testing.

#### Imported product

FSIS received a number of comments, including comments from foreign trade organizations and governments, stating that this new procedure would impact imports because imported products would need to be held at the border, which would be costly and difficult. The commenters asserted that the domestic FSIS policy that provides that establishments can move product that FSIS has tested for adulterants under their control (e.g., under company seals) should be extended to importers.

#### Response

Foreign establishments and inspection services will not be directly affected by this policy. However, the policy will affect the importer of record when FSIS tests product at the border during re-inspection. FSIS will not require the product tested by FSIS for adulterants to be held at the import establishment until results become available. When this new policy becomes effective, the

policy for imported product will be consistent with the policy for domestic product. The importer of record will be required to control all affected products that FSIS tests for adulterants during re-inspection so that they do not enter commerce until the test results are received. However, the importer of record could move the product away from the import establishment, provided the product moves under company seal or other adequate controls.

#### Controlling Product

Industry commenters raised several points regarding how FSIS expects establishments to control product. The 2011 notice explained that, consistent with current policy, establishments would be able to move product and maintain the integrity of the lot under company seal (76 FR 19955). The commenters stated that FSIS should not prescribe the specific use of company seals but should allow establishments to use any effective mechanism, which may or may not include company seals.

Industry commenters also questioned the statement in the Federal Register notice that establishments could not transfer ownership of product until it received negative test results (76 FR 19955). The commenters held that strict application of this approach would force an unnecessary change in business practices. The commenters



stated that the critical issue is not one of ownership, but one of product control.

Lastly, several industry commenters expressed concerns with the statement in the Federal Register notice that the pre-shipment review of records associated with the production lot will not be complete without the pending test results (76 FR 19955). The commenters stated that establishments have been operating under the Hazard Analysis and Critical Control Point (HACCP) regulations for years and most likely have a specific way to complete HACCP documentation. The commenters believed that to interrupt the establishment procedures for the pre-shipment review could cause confusion and could result in products being overlooked or mistakes in documentation.

#### Response

Establishments will need to have effective controls to prevent product that has been tested for adulterants from entering commerce before results become available. For such product, FSIS is not requiring the use of company seals, but the Agency will require establishments to document and support that they can control the product pending the availability of test results.

The statements made in the Federal Register concerning maintaining ownership of the product and not completing

pre-shipment review are consistent with current policy. Also, if ownership of the product changes, the product has entered commerce. FSIS has stated in documents (e.g., in FSIS directives, notices, and questions and answers post of the FSIS web page) that establishments may move product off-site pending final test results if they do not complete pre-shipment review or transfer ownership of the product to another entity. When an establishment completes a pre-shipment review (9 CFR 417.5(c)), the establishment indicates that it takes full and final responsibility for applying its HACCP controls to the product that it has produced. Further, if the establishment has completed pre-shipment review pending test results, and the results are positive, the establishment has produced and shipped adulterated product into commerce.

#### Confusion Regarding Certain Terminology

Industry commenters expressed concern over the use of the term "hold and test". They asserted that they would need to hold all tested products on site, and that in most cases that would be costly and extremely difficult to accomplish. Others were concerned that FSIS would place "U.S. retained" tags on product.

Similarly, industry commenters stated that the use of the term "withholding the mark of inspection" may cause

some individuals to think that the standard practice of preprinted labels with the Federal mark of inspection would be prohibited under this new policy.

Response

Establishments will not be required to hold product tested by FSIS for adulterants at the establishment, provided they have effective controls in place for it to move elsewhere under their ownership so that the product does not enter into commerce until the establishment receives negative results. Also, FSIS inspectors do not retain products tested by FSIS for adulterants pending test results; however, when FSIS inspection program personnel believe an animal may contain violative levels of residues, they will continue to deem it "U. S. Suspect," retain the carcass, and submit samples for residue testing.

FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process (76 FR 19955). FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, such product will not be eligible

for shipment into commerce until negative test results for adulterants are available.

#### Lot Definition

A number of industry commenters recommended that FSIS should better define and provide guidance on lot sizes. Commenters stated that without clear guidance on lot sizing, establishments risk non-compliance if they do not have a supportable basis for defining the sampled lot. Many commenters also recommended that FSIS better train its inspectors on lot-size definitions.

#### Response

The establishment is responsible for having a supportable basis to define the sampled lot. FSIS has developed compliance guidance and questions and answers for ways to determine lot sizes based, in part, on establishing microbiological independence of one production lot to another. For drug residues, lots typically are determined on a carcass basis during the slaughter operation, unless there is evidence of flock or herd application of a drug treatment. Additionally, FSIS has provided its inspection program personnel with the necessary implementation issuances for them to assess how establishments may determine lot size.

For E. coli 0157:H7, prior to FSIS's sampling, inspection program personnel inform the establishment that it is responsible for defining the sampled lot. Some factors or conditions that the establishment should consider in defining the sampled lot include scientific, statistically-based sampling programs for E. coli 0157:H7 that the establishment may use to distinguish between segments of production; Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs used to control the spread of E. coli 0157:H7 cross-contamination between raw beef components during production; processing interventions that limit or control E. coli 0157:H7 contamination; and whether beef manufacturing trimmings and other raw ground beef components or rework are carried over from one production period to another.

FSIS does not recognize "clean-up to clean-up" alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. Rather, establishments should consider whether the same source materials are used during different production periods.

For testing of ready-to-eat product or contact surfaces for Listeria monocytogenes or for testing such product for

Salmonella, inspection program personnel also inform the establishment that it is responsible for determining the lot. In contrast to E. coli O157:H7, for these types of testing, the sampled lot is generally considered the ready-to-eat product that is produced from clean-up to clean-up because the product typically undergoes consistent cooking and other lethality procedures during the production period.

#### Applying the Policy to Establishment Testing

Most industry commenters were against FSIS extending the new policy to establishment testing, although some consumer and trade organization groups thought the policy should apply to establishment testing. The commenters opposed were concerned that imposing this policy on establishment testing may cause them to test their own product less often.

#### Response

At this time, the policy will apply only to product that FSIS tests for adulterants. However, FSIS will monitor the situation to track how often establishments release product into commerce before establishment test results for adulterants become available. If an establishment tests its product for an adulterant, releases the product into commerce, and results are positive, FSIS

will request that the establishment recall the product. FSIS is aware of the impact of establishment verification testing on resources, particularly related to storage and handling and product shelf-life. Nonetheless, establishments should design their food safety system within their available resources to take all necessary and practical steps to ensure that only safe product enters commerce.

#### Economic Adulteration

Some industry commenters raised concerns about the new policy extending to economic adulteration. The commenters stated that FSIS testing for economic adulteration (e.g., protein-fat-free, moisture in hams) is infrequent. The commenters requested that FSIS clarify whether or not this testing would fall under this new policy.

#### Response

As stated in the 2011 Federal Register notice, FSIS testing that indicates product is economically adulterated would be subject to the actions outlined in this document, and, therefore, establishments will be required to control such products from entering commerce that FSIS tests for economic adulterants until negative results become available (76 FR 19953). As stated in the

2011 Federal Register notice, FSIS conducts minimal testing for economic adulteration (76 FR 19953).

#### Retail Exempt

Some industry commenters asked whether the new policy would apply to retail exempt facilities, (e.g., grocery stores) as defined in 9 CFR 303.1(d) & 381.10(d). These commenters noted that FSIS samples ground beef product at retail for Agency E. coli O157:H7 testing.

#### Response

Meat and poultry products prepared at retail exempt facilities come from federally or state-inspected source materials. Such source material would already bear the Federal or State marks of inspection when it arrives at retail. Therefore, this new policy does not directly affect retail exempt facilities as the marks of inspection are not applied at retail.

However, when FSIS OPEER Investigators sample raw ground beef for E. coli O157:H7 at retail facilities that grind raw beef products, the Agency recommends the facility hold the raw ground beef product pending Agency test results to prevent the need for a recall.



## Comments Recommending Additional Agency Measures

Some consumer group commenters who supported the policy stated that FSIS needs to pursue more rapid testing, define more pathogens as adulterants, test 100% of trim for E. coli O157:H7, and increase its trace back abilities. Also, a commenter stated that the new policy should apply to the residue testing of poultry carcasses. The commenter believed this to be necessary because of the use of arsenic-based drugs in poultry feed.

## Response

FSIS testing programs are integral to the day-to-day inspection program and verification activities of FSIS inspection program personnel in official establishments. While the establishment is responsible for ensuring that the product it produces is safe, FSIS testing is an important activity to verify whether the establishment's HACCP system ensures the production of unadulterated product. In addition, FSIS has declared six non-O157 shiga toxin producing E. coli (non-O157 STEC) to be adulterants in non-intact raw beef products and raw beef products intended for non-intact use (76 FR 72331). FSIS recently improved its traceback procedures because, starting in 2010, the Agency began collecting supplier information at the time it collects ground beef and bench trim samples for

E. coli testing. Furthermore, FSIS recently announced additional new traceback procedures and new recall procedures it intends to implement (77 FR 2675).

FSIS has consulted with the Food and Drug Administration (FDA) in regard to use of arsenic-based drugs in poultry feed. Based on the sponsor's voluntary suspension of the U.S. sales of the primary arsenic product approved for use in poultry, 3-Nitro (Roxarsone), FDA does not expect residues to be an issue of concern. Therefore, as stated in the 2011 Federal Register notice, because of the significant number of poultry carcasses in a lot, the economic effect of holding such a lot, and because, historically, FSIS has not seen residue problems in poultry tested for residues, such product will not need to be held from commerce pending negative test results. If FSIS were to find violative residues in poultry, FSIS would, of course, reconsider this issue.

#### Enforcement

Some industry commenters stated that the Agency was silent on the potential penalties FSIS would issue should an establishment not comply with these new requirements and requested that FSIS specify the penalties that will apply.

#### Response

When this policy becomes effective, FSIS will follow its regulations at 9 CFR part 500, Rules of Practice. If an establishment fails to prevent products tested by FSIS for adulterants from entering commerce before negative test results are received, the establishment may have produced and shipped adulterated or uninspected product. In this situation, the Office of Field Operations would take appropriate enforcement action (e.g., immediately suspending inspection or issuing a Notice of Intended Enforcement Action). Also, FSIS will request a voluntary recall of product, detain the product in commerce, or institute other product control actions if necessary. FSIS will consider additional enforcement actions or sanctions when necessary.

#### Downstream Testing

Some industry commenters stated that if the policy is implemented, FSIS would need to consider what product is subject to the policy if the agency samples products downstream. They stated that if samples are taken downstream, the policy should only apply to the last establishment where FSIS tested product. As an example, they stated that if a distributor sells products (e.g., trim in small boxes), which in turn may be tested at a further processor, the lot subject to control is the lot

produced at the further processor, not the product disseminated by the distributor.

#### Response

The establishment responsible for controlling product tested by FSIS is the establishment where FSIS collects the sample. (Note that FSIS tests beef manufacturing trimmings at the slaughter establishment, not at a further processor.) However, if a further processor grinds the trim or produces bench trim from materials derived from cattle not slaughtered on site at that establishment, FSIS may sample such product.

Nevertheless, FSIS, through its trace-back activities, seeks to determine the facts associated with contamination. In most cases, FSIS' objective is to identify the most likely point in the production process at which contamination occurred, e.g., the slaughter dressing operation. Therefore, if FSIS finds ground beef or bench trim positive at a further processor, FSIS conducts follow up testing and other verification activities at the slaughter establishment that supplied the source materials. In addition, each point in the production process affords an opportunity for the subsequent establishments and operations handling the product (e.g., including retail) to exert control to ensure that the product is not

adulterated. Thus, FSIS takes appropriate action to ensure that all handlers of the product are complying with the requirements of the inspection laws and regulations.

#### Summary and Conclusion

After consideration of all comments and for the reasons discussed above, FSIS will implement a new policy that requires official establishments and importers of record to maintain control of product tested for adulterants by FSIS and not allow such products to enter commerce until negative test results are received. The policy applies to non-intact raw beef product or intact raw beef product intended for non-intact use that is tested by FSIS for STECs. Also, the policy applies to any ready-to-eat products tested by FSIS for pathogens. Similarly, this policy applies to ready-to-eat product that passed over food-contact surfaces that have been tested for the presence of a pathogen by FSIS. This policy does not cover raw meat or poultry products tested for Salmonella or other pathogens that FSIS has not determined to be adulterants of those products.

The new policy also applies to livestock carcasses subject to FSIS testing for veterinary drugs, such as antibiotics, sulfonamides, or avermectins or the feed additive carbadox.

Finally, FSIS testing that indicates product is economically adulterated would be subject to the actions outlined in this document, and, therefore, establishments will be required to control such products from entering commerce that FSIS tests for economic adulterants until negative results become available.

#### Costs and Benefits

The discussion below is consistent with the discussion of costs and benefits in the 2011 Federal Register notice. However, it has been updated to include 2010 recall data and new Cost of Illness per case numbers updated in April, 2012. The new estimates represent a lower bound for an average cost of illness because they only include medical costs and loss-of-productivity costs. They do not include pain and suffering costs. Complete 2011 recall data was not available at the time this notice was developed. FSIS did not update the cost estimates from the 2011 Federal Register notice because these data either do not change significantly from year to year or more updated data are not currently available.

In addition, FSIS did not consider non-O157 STEC in the benefits and costs analysis. In June 2012, FSIS began testing for six non-O157 STEC in raw beef manufacturing trimmings. Although FSIS anticipates additional public

health benefits will accrue as a result of establishments maintaining control of such products tested by FSIS until negative results for non-O157 STEC become available, there is not enough data to accurately estimate benefits at this time. As for the costs, there would be no change from the numbers presented in this analysis. All of the costs associated with the implementation of the Agency's testing for non-O157 STEC are captured within the estimates for E. coli O157:H7 in raw, non-intact beef products (Group 1, Table 3). When FSIS collects samples of beef manufacturing trimmings, it tests them for both E. coli O157:H7 and non-O157 STEC.

Expected Benefits of the Action:

The Agency expects benefits from this policy to accrue to consumers, Government, and industry.

If an establishment fails to hold a product when FSIS tests for a pathogen, and the test is positive, the establishment will be asked to recall the product. Because the pathogens for which FSIS does testing represent an immediate threat to human health, the recall would be classified as a Class I recall.<sup>1</sup> Table 1 shows Class I recalls (2007-2010) for FSIS testing that are included in

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<sup>1</sup> There are three classes of recalls. Class I: a health hazard situation where there is a reasonable possibility that the use of the product will cause serious, adverse health consequences; Class II: a health hazard situation where there is a remote probability of adverse health consequences from the use of the product; and Class III: a situation where the use of the product will not cause adverse health consequences.

the universe for this policy analysis. These recalls were for E. coli O157:H7, Listeria monocytogenes (Lm), and Salmonella in RTE product. In 2007 there were 14 Class I recalls as a result of FSIS testing; in 2008 there were 19 Class I recalls; in 2009 there were 11 Class I recalls; and in 2010 there were 5 Class I recalls. In 2007 seven of the Class I recalls were for E. coli O157:H7 and seven for Lm. In 2008, seven of the Class I recalls were for E. coli O157:H7 and twelve for Lm. In 2009, eight of the Class I recalls were for E. coli O157:H7, and three were for Lm. In 2010, one of the Class I recalls was for E. coli O157:H7, three for Lm, and one for Salmonella in Ready-to-Eat (RTE).

Table 1. Class 1 Recalls included in Test-and-Hold policy Universe derived from FSIS Tests. (2007-2010)

Year and Type	<u>E. coli</u> O157:H7	<u>Lm</u>	<u>Salmonella</u>	<u>TOTAL</u>
2007				
FSIS	7	7	0	<b>14</b>
2008				
FSIS	7	12	0	<b>19</b>
2009				
FSIS	8	3	0	<b>11</b>
2010				
FSIS	1	3	1	<b>5</b>
<b>TOTAL:</b>	<b>23</b>	<b>25</b>	<b>1</b>	<b>49</b>

NOTE: Data source FSIS recall division.



If the combination of industry and Government costs per recall on average is \$1 million,<sup>2</sup> then the total annual cost of FSIS recalls could be on average as high as \$12 million per year.<sup>3</sup>

Considering costs to retailers as well as manufacturers and State, local, and Federal authorities, a class I recall may cost as much as \$3 million to \$5 million.<sup>4</sup> Using a conservative estimate, if the actual cost of a recall for industry and government combined is closer to \$3 million than \$5 million,<sup>5</sup> then the annual cost of the recall (the benefit of avoiding these recalls) could be as high as \$37.0 million annually (49 recalls /4 years\* \$3 million).

In addition to the cost savings attributed to avoiding recalls described above, firms generally suffer a loss of sales, at least temporarily, following a Class I or Class II recall. This alone does not result in a social cost, but rather a social transfer, as other firms will step forward to capture sales lost by the recalling firm.

However, in addition to the resources invested in recalling

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<sup>2</sup> “Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products” (63 FR 24258; May 1, 1998).

<sup>3</sup> The annual figure of \$12 million is derived by summing the total number of FSIS recalls for 2007-2010 from Table 1, then multiplying the total by \$1 million which is the average cost per recall for industry and government. That figure is then divided by 4 to get the annual amount.  $(14 + 19 + 11 + 5 = 49 * 1M = 49M / 4 = \$12.3 \text{ M per year, which is then rounded to } \$12 \text{ M})$ .

<sup>4</sup> “Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products” (63 FR 24258; May 1, 1998).

<sup>5</sup> Ibid

the product, the recalling firm may incur additional advertising costs to recapture the loss of sales plus the flow of future sales, which is a social cost. Additionally, there can be a loss of reputation for the manufacturer and the brand associated with recalls that may affect future sales.

#### Consumer

FSIS expects the consumer to benefit from: 1) reduced incidence of adulterated product being released into commerce, 2) fewer recalls resulting in higher confidence and acceptability of products, and 3) lower levels of illness. This new policy will lead to increased consumer confidence and acceptance of product through reduced recalls and negative press.<sup>6</sup>

#### Government

FSIS expects there to be a reduction in the number of recalls, and, therefore, the Agency expects to benefit from lower Agency costs for recalls and recovery of adulterated product because of: 1) reduced inspection program personnel activities at Federal establishments, 2) reduced overtime

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<sup>6</sup> Ollinger, Michael, working paper. "Many economists have examined the effects of reputation loss and the production of unsafe food. Packman (1998) argues that the negative publicity generated from a recall can erode prior investments in reputation and brand capital. Economists (Thomsen and McKenzie, 2001; Pruitt and Peterson; Salin and Hooker) found that firms that voluntarily recalled contaminated meat and poultry products suffered a decline in long run profitability (i.e., significant declines in stock prices). A number of studies (Piggott and Marsh, 2004; Marsh, Schroeder, and Mintert, 2004) determined that adverse meat and poultry food safety events led to temporary declines in meat and poultry consumption. Thomsen, Shiptsova, and Hamm (2006) established that sales of branded frankfurter products declined more than 20 percent after product recalls."

hours for FSIS staff, and 3) reduced staff travel to establishments after recalls to conduct Food Safety Assessments (FSA) and recall effectiveness checks. These expenses would include air, train, or car travel; lodging; and per diem expenses for meals. In addition, FSIS should have less need to disseminate information about food recalls through press releases and recall releases.

#### Industry

Under this policy change, the meat and poultry processing and slaughter industries will benefit from fewer recalls and negative press. As the number of recalls decline, there will likely be: 1) an increase in consumers' confidence, 2) reduced costs for recalls, and 3) greater consumer acceptance of products.

Initially, preventing adulterated product from going into commerce should reduce operating costs. Operating costs will be lower because companies will be less likely to have a recall and experience the adverse impacts to business reputation as well as the product loss associated with a recall. Avoiding adverse impacts on business reputation is an indirect benefit.

#### Imported Product

There were 11 Class I recalls of FSIS tested imported product for the 2007-2010 (Table 1) time period, 4 for E.

coli O157:H7 and 7 for Lm. One recall occurred in 2007, (Lm), eight in 2008 (4 for E. coli O157:H7 and 4 for (Lm)) and two in 2010 (Lm). There were no recalls from FSIS testing for imported product in 2009. All of these recalls are included within the universe described in Table 1 and therefore are included in the Benefits section within this analysis.

#### Human Health Benefits.

##### Introduction:

The Centers for Disease Control and Prevention (CDC) has estimated that Shiga toxin-producing E. coli O157:H7 infections cause 63,000 illnesses annually in the United States, resulting in more than 2,138 hospitalizations and 20 deaths.<sup>7</sup> The Economic Research Service (ERS) estimates that the annual economic cost of illness caused by E. coli O157:H7 is \$489 million<sup>8</sup> (in 2010 dollars) for all cases, not just for foodborne cases.

The occurrence of recalls demonstrates that pathogens have been present on raw meat and poultry products distributed in commerce under FSIS's existing approach.

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<sup>7</sup> Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. "Foodborne Illness Acquired in the United States—Major Pathogens". Emerging Infectious Diseases. 2011 January. Table 2 of this report provides foodborne STEC O157:H7 illnesses at: 63,153, with 90% confidence of (17,587-149,631). Table 3 of this report provides STEC O157:H7 hospitalizations at 2,138, with 90% confidence of (549-4,614) and deaths of 20, with 90% confidence of (0-113).

<sup>8</sup> Frenzen, Paul D., Drake, Alison, Angulo, F.J., and the Emerging Infections Program Foodnet Working Group. Journal of Food Protection, Vol. 68 No. 12, 2005, pp. 2623-2630.

These pathogens represent a hazard to human health. Thus, public health likely will benefit because meat and poultry products will be held until results of pathogen tests are returned as negative. If test results are positive, the product will be destroyed or further processed to destroy the pathogen, rather than having to be recalled. This change will thus reduce foodborne pathogens in products that are released into commerce. The economic health benefits are expected to be small relative to the economic benefits of avoided recalls.

To reach this conclusion FSIS analyzed both the actual illnesses from the universe described in Table 1 and estimated future illnesses averted as a result of this change. We discuss in Section A (Potential averted illnesses from this policy using actual case data) the research conducted by the Economic Research Service (ERS) for each of the pathogens, E. coli O157:H7, Lm, and Salmonella, as well as their associated costs per case.<sup>9</sup>

A. Potential averted illnesses from this policy using actual case data.

1) During 2007-2010, there were 23 recalls for E. coli O157:H7 from FSIS testing. None of these recalls resulted in any illnesses according to FSIS's Office of

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<sup>9</sup> ERS cost calculator can be found on their Web site at [http:// www.ers.usda.gov](http://www.ers.usda.gov)

Public Health Science (OPHS) data. The ERS estimate excludes a number of other potential costs, such as those for special education, nursing homes, travel, childcare, and pain and suffering. Illnesses for E. coli O157:H7 are divided into seven severity levels depending on whether the patient visits a physician or not, develops Hemolytic Uremic Syndrome (HUS) or not, develops End-stage renal disease or not, and finally whether death occurs. For each of these classes, ERS derives an average cost of illness. The CDC classifies illnesses into three classes: death, hospitalizations, and other.<sup>10</sup> FSIS used these classifications and the percentages of cases identified in them to estimate \$3,281 as the average cost per case.<sup>11</sup>

2) During 2007-2010 there were 25 recalls for Lm from FSIS testing. Only one of these recalls was associated with illnesses. In 2008, there were two illnesses, one of which was fatal, when a customer consumed chicken salad that had been released into commerce before the FSIS test results were returned as positive. The cost of Lm illness

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<sup>10</sup> Scallan E, Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et. al. "Foodborne Illness Acquired in the United States—Major Pathogens". Emerging Infectious Diseases. 2011 January.

<sup>11</sup> The FSIS estimate for the cost of E. coli O157:H7(\$3,281 per case, - 2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: STEC O157 (June 2011). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for STEC O157. Scallan E, Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et. al. "Foodborne Illness Acquired in the United States—Major Pathogens". Emerging Infectious Diseases. 2011 January.

is \$1.3 million per case.<sup>12</sup> Benefits from averting the two illnesses had the establishment held the product until the test results returned a positive would be \$2.6 million (\$1.3 M \* 2), or \$650,000 annually.

3) There was one recall from FSIS testing for Salmonella in RTE product during 2007-2010. Research has shown that the cost per case of a Salmonella illness is \$2,423, or \$606 annually.<sup>13</sup>

B. Estimated averted illnesses from this policy:

FSIS has developed a model<sup>14</sup> to estimate annual illnesses averted per positive sample from holding FSIS tested product until testing results are returned. This model is based on 2007-2010 recall data, as well as the OPHS illness data occurring from these recalls.<sup>15</sup> The model estimates expected illnesses by accounting for volume of product recalled and "time in days" between the dates of production of adulterated product until the date of recall

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<sup>12</sup> The FSIS estimate for the cost of *Lm* illness (\$1.3 million per case – 2010 dollars) is based on a model developed by Buzby, et al. (1996). The Buzby model is limited to medical costs and productivity loss. Therefore, in order to account for death, FSIS incorporated the value of statistical life in the overall cost calculation. Buzby, J.C., T.C. Roberts, J.T. Lin, and J.M. MacDonald. 1996. "Bacterial foodborne disease: medical costs and productivity losses". U.S. Department of Agriculture, Economic Research Services, AER-741. U.S. Department of Agriculture, Washington, DC.

<sup>13</sup> The FSIS estimate for the cost of *Salmonella* (\$2,423 per case – 2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: *Salmonella* (June 2011). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for *Salmonella*.

<sup>14</sup> See Appendix 1: "Development of model for predicting averted illnesses due to *E. coli* O157:H7 from Test and Hold" and Appendix 2: "Data used in Analysis." A copy of these documents are available for viewing in the FSIS Docket Room and on the FSIS Web site as related documents associated with this docket.

<sup>15</sup> OPHS data was used for the model that contained illnesses from all recalls and all sources. This included Outbreak, Illness, FSIS Test, and Establishment Test. This was done only for the purpose of estimating the rational expectation of future illnesses averted by this policy.

of that adulterated product. With this policy in effect, the FSIS model estimated the upper 95% confidence bound of averted E. coli O157:H7 illnesses to be approximately 3.07 for a four year period (based on the 2007-2010 data). FSIS estimated human health benefits, based on averting these 3.07 E. coli O157:H7 illnesses to be approximately \$2,518 annually ( $\$3,281 \times 3.07/4$ ).

Using similar methodology and an estimated number of illnesses of 0.32 for Listeria monocytogenes and .34 for Salmonella, in RTE product, the annual cost is \$104,000 and \$206 respectively. For the three pathogens, E. coli O157:H7, Listeria monocytogenes, and Salmonella human health benefits are estimated from the model to be approximately \$106,724 annually. See Table 2.

Table 2. Human health benefits from actual recalls and estimated model (2007-2010).

Pathogen	Cost per Case	Actual Cases 2007-2010	Actual Annual Benefit 2007-2010	FSIS Estimated Cases Averted (Model) 2007-2010 **	Annual Benefit (Model)
E. coli O157:H7	\$3,281	0	\$0	3.07	\$ 2,518
Listeria Monocytogenes	\$1.3 M	2	\$650,000	.32	\$104,000
Salmonella	\$2,423	0	\$0	.34	\$206
TOTAL			\$650,000	3.73	\$106,724
* NOTE: LM is known to have a high death rate and as such one death is included in the expectation of benefits from illnesses averted.					
** Table 3 of the Model (Appendix) estimates illnesses for 10 years. To make the numbers comparable we used estimated illnesses from the model/10*4 to derive the numbers in this column.					



Total human health benefits from the FSIS model and actual reported illnesses combined would be approximately \$756,724 annually (\$650,000 + \$106,724). Differences may be due to rounding.

Residue Benefits:

Microbiological hazards are expected to drive the cost-benefit analysis because they result in an attributable short term, low (morbidity) to high (morbidity) impact consequences that can be realistically estimated.

The cost-benefit analysis for chemical hazards on the other hand is difficult to quantify. The negative health effects of exposure to low levels of chemicals are long term and multifactorial. Single exposure to low levels of chemicals or cumulative exposure can contribute to negative health affects for example, cancer, 10, 20, or more years later. Of course, over such long periods of time, individuals are exposed to a variety of hazards making it impossible to quantify the contribution of the chemical exposure to societal and medical costs. The approach for conducting a cost benefit analysis for single incidents of contamination at levels that cause immediate morbidity or mortality, i.e., where the health effects are readily

attributable to the exposure, is comparable to microbiological hazards.

The Food and Drug Administration (FDA) conducts risk assessments to establish what level of chemical residues in food has a reasonable certainty of no harm when consumed by humans.<sup>16</sup> They consider acute and chronic exposure scenarios to set residue limits and include a wide margin of safety in their calculations. Meat, poultry, and egg products with chemical residues that exceed the tolerances or other limits set, or for which no scale level has been set, by EPA and FDA are adulterated and unsafe for human consumption.

#### Summary of Benefits.

The annual benefits from this policy change come from:

- 1) Reduced costs of recalls, \$12 million to \$37 million,
- 2) Actual averted illnesses, \$650,000 as shown in Table 2, and
- 3) Estimated Averted illnesses for E. coli O157:H7, Listeria monocytogenes and Salmonella of \$106,724 as shown in Table 2.

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<sup>16</sup> See General Accounting Office (GAO) report "Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies", GAO-01-810, August 2001 at <http://www/gao.gov/new.items/d01810.pdf>

Total benefits from this policy change are estimated to range between \$12.8 million and \$37.8 million annually.

Expected Costs of the Action:

FSIS prepared a paper in September, 2006 to provide data on trends in the industry practice of holding meat and poultry products pending results of FSIS microbiological testing.<sup>17</sup> Identifying trends in industry holding practices provides a context and baseline for any future evaluation of the effects of holding product pending test results. FSIS examined test data for the calendar years 2003 through 2005, as well as data for the first eight months of 2006, and grouped data by establishment size and pathogen. Specifically, FSIS examined the hold/release information included with FSIS testing results for the following pathogens in five different groups: 1) E. coli O157:H7 in raw, non-intact beef produced by domestic official establishments;<sup>18</sup> 2) E. coli O157:H7 in domestically-produced RTE meat and poultry; 3) Salmonella in domestically-produced RTE meat and poultry; 4) Lm in domestically-produced RTE meat and poultry; and 5) Lm on food-contact surfaces in establishments that produce RTE meat and poultry products.

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<sup>17</sup> A summary of the FSIS's analysis is available electronically at [http://www.fsis.usda.gov/OPPDE/NACMPI/May2006/Test\\_and\\_Hold\\_Report\\_NACMPI.pdf](http://www.fsis.usda.gov/OPPDE/NACMPI/May2006/Test_and_Hold_Report_NACMPI.pdf)

<sup>18</sup> In this paper, FSIS did not examine results from the recently initiated FSIS baseline testing of beef trim for E. coli O157:H7 and Salmonella.

## A. Domestic Product

### 1) Micro testing

FSIS found the following results of meat and poultry product being held by establishments prior to receiving FSIS test results. Table 3 shows the results by establishment size for the first 8 months of year 2006 for the five test groups described above.

Table 3. Percent of Product being held by establishment size for 2006 (Jan-Aug).

	Large	Small	Very Small	Unknown
Group 1	100%	83%	79%	57%
Group 2	100%	93%	88%	100%
Group 3	100%	90%	82%	93%
Group 4	99%	91%	82%	93%
Group 5	100%	97%	88%	----

Group 1: Percent of raw, non-intact beef Products held after Agency E. coli O157:H7 Sampling.

Group 2: Percent of RTE Products held after Agency E. coli O157:H7 Sampling.

Group 3: Percent of RTE Products held after Agency Salmonella Sampling.

Group 4: Percent of RTE Products held after Agency Lm Product Sampling.

Group 5: Percent of RTE Products held after Agency Lm Food Contact Surface Sampling.

Note: This data is the latest available data for product held in establishments from FSIS testing. Study by the Office of Program, Evaluation, Enforcement, and Review (OPEER.).

In evaluating recent data, the Agency has noted that establishments' releasing product into commerce before receiving test results continues to be a problem.

However, using the percentage numbers from Table 3 for the first eight months of 2006 will provide a basis for establishing the costs for 2007-2010 to hold product until test results are returned.

Table 4 shows the number of Federally inspected meat and poultry establishments by establishment size and presents in columns 3 and 4, based on the results from Table 3, the number of establishments currently holding product, as well as the number of establishments that will need to hold product as a result of this policy change.

Table 4. Federal Inspected Meat/Poultry Establishments.

ESTABLISHMENT SIZE (1)	NUMBER of ESTABLISHMENTS * (2)	HOLDS PRODUCT (3)	DOES NOT HOLD PRODUCT (4)
LARGE	362	362	0
SMALL	2,366	1,964 - 2,295	71 - 402
VERY SMALL	2,900	2,291 - 2,552	348 - 609
UNKNOWN	578	329 - 578	0 - 249
<b>TOTAL:</b>	6,206	4,946 - 5,787	419 - 1,260

\* Source: Performance Based Inspection System (PBIS) 1/3/2008. There has been no substantial change in establishment numbers.

The data provided in Table 3 are used to calculate the number of establishments holding product (column 3) and the number of establishments not holding product (column 4).

Across establishment size, between 79 percent and 100 percent of establishments already hold product pending test results, and between zero and 21 percent will need to hold product pending test results.

From the enumerations shown in Table 4, FSIS assumes, for cost purposes only, that all 362 large establishments are holding all tested product for results. Approximately

71 - 402 small establishments, 348 - 609 very small establishments, and between 0 and 249 unknown size establishments do not hold tested product and will be affected by this new policy. Table 4, column 4 shows the range of establishments that will have to hold product pending test results before FSIS will apply the USDA mark of inspection. A total of between 419 and 1,260 federally inspected meat and poultry establishments will be affected by this policy change. There will be no additional costs to any of the large establishments as they are assumed to hold all tested product. FSIS expects that among the remaining establishments that do not hold tested product, there will be an adjustment of lot size to accommodate necessary storage capacity at the establishment prior to an FSIS test.

FSIS conducted further research on all FSIS tests conducted in the year 2007. Combining the percentages of product held from Table 3 and the estimates of common lot sizes from the following Table 5, FSIS reached certain conclusions about the additional pounds of product that would need to be held by the small and very small establishments which is shown in Table 6.

Table 5. Estimated Lot Sizes by Establishment Size.

ESTABLISHMENT SIZE	LOT SIZE PRODUCED	AVERAGE LOT SIZE TESTED *
LARGE	2,000-30,000 pounds	2,000 pounds
SMALL	1,000-10,000 pounds	1,000 pounds
VERY SMALL	50-2,000 pounds	50-60 pounds

Source: Common Industry Practice and expert elicitation.

\* Tested lots are smaller than typical production lot sizes.

FSIS estimates the common industry practice for average lot sizes tested to be approximately 2,000 pounds at large establishments, 1,000 pounds at small establishments, and between 50-60 pounds at very small establishments. As a result of the above lot size estimations, there may be a certain number of small and very small establishments that will incur costs relative to additional storage (recurring costs) or for capital equipment (one-time costs), in order to hold tested product.

Table 6. Additional cost per establishment to hold estimated pounds of product.

	Lbs to be held by Est.	Days Product to be held	Cost per Est. to Store Product
LARGE	0	3-8	\$0
SMALL	4,511	3-8	\$5,000
V/SMALL	1,329	3-8	\$1,000
UNKNOWN	1,011	3-8	\$1,000

Source: FSIS/OPEER/OCIO data.

Cost per commercial freezer @ \$5,000 per 300 cu. ft. for small establishments. Cost of stand-up freezer for very small establishments @ \$1,000.

Factors affecting this cost impact include: 1) the amount of product needed to be handled and placed into storage; 2) the average number of days of storage; 3) the number of times per year that tests occur; and 4) the cost per day in handling and storage.

The costs shown in Table 6 would predominately be one-time capital expenditures to purchase freezers for storage of tested product. There will be a small amount of electricity charges to operate the refrigeration units, but we do not anticipate that they would be significant. Labor costs would also be minimal to accommodate the additional product stored. Additionally, FSIS recognizes the concern of some very small establishments that they could lose some product because of the product's short shelf life, and that an establishment could experience some inability to satisfy customer orders, resulting in a short-term disruption in business activities.<sup>19</sup> FSIS does not have sufficient information to include costs associated with this disruption in the analysis.

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<sup>19</sup> The American Meat Institute (AMI) survey dated April, 2007, conducted for the Lm Final Regulatory Impact Analysis shows various amounts reported for spoilage due to products exceeding shelf-life prior to obtaining test results or diminished shelf-life after obtaining test results for Lm. Large establishments report a range of \$0-\$50,000 or on average \$3,571 and a median of \$0; small establishments report a range of \$0 - \$150,000 or on average \$5,750 and median of \$0; and very small establishments report a range of \$0 - \$5,000, or on average \$450 and a median of \$0. Only 16 very small and 75 small establishments responded to the survey. There are 2,900 very small and 2,366 small federally inspected establishments from PBIS data.



Table 7 combines the results of tables 4, 5 and 6 and shows that the estimated total costs to all small and very small (and unknown) establishments that do not hold product domestically would range between \$703,000 and \$2.87 million.

Table 7. Total one-time cost per establishment size.

<b>Est. Size</b>	<b># Est. Affected</b>	<b>Cost/Est. to Store Product</b>	<b>One-time Total Cost to Hold Product *</b>	<b>Annualized 7% - 10 yrs.</b>
Large	0	\$0	\$0	\$0
Small	71-402	\$5,000	\$355K - \$2.01M	\$50,541 - \$299,000
Very Small	348-609	\$1,000	\$348K - \$609K	\$49,545 - \$86,700
Unknown	0-249	\$1,000	\$0 - \$249K	\$0 - \$17,227
TOTAL	419-1,260		\$703,000 - \$2.87 M	\$100,000 - \$408,600

\* NOTE: Total cost to hold product is result of # of Establishments affected \* cost/Est to store product.

## 2) Residue Testing:

The National Residue Program (NRP) consists of two sampling plans: domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes both a scheduled sampling program that is derived statistically by an interagency (FSIS, EPA, and FDA) technical team and by inspector generated sampling in which samples are collected by in-plant veterinarians when they suspect an animal presented for slaughter may have violative levels of

chemical residues. The import re-inspection sampling plan verifies the equivalence of inspection systems of exporting countries. FSIS inspectors collect samples randomly from imported products, and the intensity of sampling increases when products fail to meet U.S. requirements.

Residue Costs:

In CY 2008, under the National Residue Plan, there were 22,709 FSIS residue samples completed. An additional 135,552 inspector-generated samples were taken. The number of samples includes those taken in-plant, taken from show animals, taken by inspectors or OPEER personnel as part of their regular work, and as part of state programs.

The average range of days between a sample arriving at the lab and the report being available is generally 3-10 working days. Some screen results are available the same day by Kidney Inhibition Swab (KIS), tests, while other tests may take longer than 10 days.

The Agency does not anticipate any substantial cost impact from additional storage space requirements for FSIS residue testing. For establishment residue testing, the establishment as part of its HACCP program should already be holding any tested carcasses.

Products will have a reduced shelf-life at retail as a result of carcasses being held pending FSIS and

establishment test results. Some beef product that has been residue tested and held for three to ten days will lose freshness and will need to be frozen. Over the past nine years, on average, the difference in fresh vs. frozen beef prices is approximately \$0.054 a pound.<sup>20</sup> The worst case scenario for loss of business revenue for dairy cows, used for beef estimation purposes, would be approximately \$39,500.<sup>21</sup> While these lost revenue estimates are a worst case scenario, we also estimate the range for reduced beef sales to be between \$19,700 and \$39,500.

Additionally, roaster pig carcasses could go rancid and would also need to be frozen. Some product will go to secondary markets, such as renderers, pet foods, and fertilizer product. For roaster pigs, we estimate a worst case scenario loss of business at approximately \$92,400.<sup>22</sup> The lower estimate for roaster pigs is \$46,200.

Table 8. Loss of revenues for domestic beef and roaster pigs due to Residue test and hold policy.

Est. Size	Beef # of Establishments	Beef \$\$ Lost	Roaster Pigs # of Est.	Roaster Pigs \$\$ Lost
Large	132	\$1,264	4	\$601
Small	810	\$7,900	85	\$13,860

<sup>20</sup> Beef price data provided by the Economic Research Service, USDA. The data is for 90% lean beef, not carcasses and can be interpreted as cents per pound or dollars per cwt of product.

<sup>21</sup> Estimation of worst case business loss for dairy cows: total number of animals selected for dairy cows (300) \* 4 (number of chemicals sampled) \* average lbs of animal (609) = total lbs to be held \* price difference per lb. from fresh to frozen (\$0.054)

<sup>22</sup> Estimation of worst case business loss for roaster pigs: total number of animals selected for roaster pigs 300 \* 4 (number of chemicals sampled) \* average lbs of animal (70) = total lbs to be held \* price per lb. (\$1.10)

Very Small	3164	\$30,099	467	\$77,616
Unknown	25	\$237	2	\$323
<b>TOTAL</b>	<b>4131</b>	<b>\$39,500</b>	<b>558</b>	<b>\$92,400</b>

Source of data: Data Analysis Integration Group (DAIG) and Office of Policy and Program Development (OPPD)/Risk Management Division.

## B. Imported Product

### Imported Re-inspection Sampling Plan.

Import Inspection Personnel are to sample imported ready-to-eat (RTE) meat and poultry products produced in foreign establishments. Analyses will include Lm and Salmonella testing for all RTE products, and E. coli 0157:H7 for cooked beef patties and dry or semi-dry fermented sausages.

Ready-to-eat cooked meat or poultry product is subjected to microbial sampling at the port-of-entry. This includes any product that is intended to be consumed without any further safety preparation steps.

Table 9 describes the two different types of tests that are conducted on imported product, 1) micro testing, and 2) residue testing (column 1). Column 2 shows the number of samples where product was held, while column 3 shows the number of samples where the product was not held. Column 4 shows the number of samples for which the available data do not show whether or not the product was held. Column 5 is the total of all tests taken on imported

product (sum of columns 2, 3 & 4). Column 6 is the percentage of tested product that is currently being held.

Table 9. Percent of Imported Product Held that has been FSIS Tested (by Lots).

TYPE (1)	Held (2)	Not Held (3)	Not Indicated (4)	TOTAL (5)	%age Product Currently Held (6)
Micro	1994	1799	88	3881	51.4
Residues	2320	2490	493	5303	43.7

Source: FSIS International Policy Division

Table 10 shows the type of samples (column 1) and the number of FSIS samples taken (column 2). The average lot size derived by dividing the total pounds of product presented for import in 2008 by the total lots presented for import in 2008 is shown in column 3 (3,270,643,817/210,592). Column 4 and 5 are percentage of product currently held and percentage of product to be held. Column 6 and 7 represent the total pounds to be held and the cost of holding that product. The cost of holding imported product when this policy becomes effective will range from approximately \$757,000 to \$832,000.<sup>23</sup>

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<sup>23</sup> The storage cost data was not robust, therefore a cost + 10% range was cited. Adding the 10% leads to a storage cost of \$832,242.

Table 10. Cost to Hold Imported FSIS Tested Product

TYPE	# of FSIS Samples	Avg. Lot Size	% Product Now held	Additional %age of Product to be Held *	Total Pounds to be held	Cost for Holding Product
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Microbial	3881	15,530	51.4	48.6	29,292,158	\$292,922
Residue	5303	15,530	43.7	56.3	46,366,197	\$463,662
					<b>TOTAL:</b>	<b>\$756,584</b>

NOTE: Cost is based on storage of product for up to 30 days @ \$.01/pound.

Source: FSIS - International Policy Division

\*Column 5 is the additional percentage of product that will need to be held once this policy becomes effective. (100% - column 4 %age)

#### Summary of Annual Costs:

Total Domestic Product - \$100,000 - \$408,600

Loss of Business Revenue - \$66,000 - \$131,900

Total Import Product - \$757,000 - \$832,000

Total Cost: \$923,000 - \$1.4 million

Estimated annual benefits range between \$12.8 million and \$37.8 million and exceed the estimated costs. Annual net benefits range between \$11.9 million and \$36.4 million.

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Done at Washington, DC, on: November 30, 2012

Alfred V. Almanza,  
Administrator.

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